## AP3 Rec'd PCT/PTO 3 0 MAY 2008

PTO-1390 (Rev. 02-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| TRANSMITTAL LETTER TO THE  | LP-31010-US   |  |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|--|
| DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371             |   | U.S. APPLICATION NO (Mknown see 7 SER 1.5) |  |  |  |  |  |  |
|  | <u></u>   | PRIORITY DATÉ CLAIMED                      |  |  |  |  |  |  |
| PCT/DK2004/000844  | ERNATIONAL FILING DATE<br>mber 2004   | 3 December 2003                            |  |  |  |  |  |  |
| TITLE OF INVENTION   |   |  |  |  |  |  |  |  |
| PHARMACEUTICAL COMPOSITIONS COMPRISING DANAZOL  APPLICANT(S) FOR DO/EO/US                    |   |  |  |  |  |  |  |  |
| HOLM et al.  |   |  |  |  |  |  |  |  |
| Applicant herewith submits to the United States Des  | licant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:                                      |  |  |  |  |  |  |  |
| 1. This is a FIRST submission of items concerning  | This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.  |  |  |  |  |  |  |  |
| 2 This is a SECOND or SUBSEQUENT submission  | This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.   |  |  |  |  |  |  |  |
| This is an express request to begin national example (5), (6), (9) and (21) indicated below. | This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. |  |  |  |  |  |  |  |
| 4. The US has been elected (Article 31).   | The US has been elected (Article 31).   |  |  |  |  |  |  |  |
| 5. A copy of the International Application as filed  | A copy of the International Application as filed (35 U.S.C. 371(c)(2))  |  |  |  |  |  |  |  |
| a. is attached hereto (required only if no   | a. is attached hereto (required only if not communicated by the International Bureau).  |  |  |  |  |  |  |  |
| b. has been communicated by the Inter-   | national Bureau.  |  |  |  |  |  |  |  |
| c is not required, as the application wa   | s filed in the United States Receiv   | ring Office (RO/US).                       |  |  |  |  |  |  |
| 6. An English language translation of the Internat   | An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).  |  |  |  |  |  |  |  |
| a is attached hereto.  | a. is attached hereto.  |  |  |  |  |  |  |  |
| b. has been previously submitted under   | b. has been previously submitted under 35 U.S.C. 154(d)(4).   |  |  |  |  |  |  |  |
| 7. Amendments to the claims of the International   | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))  |  |  |  |  |  |  |  |
| a are attached hereto (required only it  | a. are attached hereto (required only if not communicated by the International Bureau).   |  |  |  |  |  |  |  |
| b. have been communicated by the Inf   | b. have been communicated by the International Bureau.  |  |  |  |  |  |  |  |
| c. have not been made; however, the  | c. have not been made; however, the time limit for making such amendments has NOT expired.  |  |  |  |  |  |  |  |
| d. have not been made and will not be  | d. have not been made and will not be made.   |  |  |  |  |  |  |  |
| 8. An English language translation of the amend  | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).   |  |  |  |  |  |  |  |
| 9. An oath or declaration of the inventor(s) (35 U.  | An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).  |  |  |  |  |  |  |  |
| 10. An English language translation of the annexes Article 36 (35 U.S.C. 371(c)(5)).         | An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).                    |  |  |  |  |  |  |  |
| Items 11 to 20 below concern document(s) or infor  | tems 11 to 20 below concern document(s) or information included:  |  |  |  |  |  |  |  |
| 11 An Information Disclosure Statement under 37  | CFR 1.97 and 1.98.  |  |  |  |  |  |  |  |
| 12 An assignment document for recording. A sepa  | . An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.   |  |  |  |  |  |  |  |
| 13. A preliminary amendment.   |   | .:·  |  |  |  |  |  |  |
| 14. An Application Data Sheet under 37 CFR 1.76.   | :   |  |  |  |  |  |  |  |
| 15 A substitute specification.   |   |  |  |  |  |  |  |  |
| 16. A power of attorney and/or change of address   | A power of attorney and/or change of address letter.  |  |  |  |  |  |  |  |
| 17. A computer-readable form of the sequence list  | A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.   |  |  |  |  |  |  |  |
| 18. A second copy of the published International A   | A second copy of the published International Application under 35 U.S.C. 154(d)(4).   |  |  |  |  |  |  |  |
| 19. A second copy of the English language transla  | A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).   |  |  |  |  |  |  |  |
|  | Other items or information: Unexecuted Declaration and Power of Attorney and International Search Report  |  |  |  |  |  |  |  |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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AP20 Rec'd PCT/PTO 30 MAY 2006

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| •  | U.S. APPLICATION  | Out thown, see 37 ( 1.                           | n, See 37 (P. 1.5) INTERNATIONAL APPLICATION NO. |                        |              | ATTORNEY'S DOCKET NUMBER |  |  |  |
|--|---|--|--|------------------------|--------------|--------------------------|--|--|--|
|  |   | 9011/0   | PCT/DK2004/                                      | 000844                 | LP-31010-US  |                          |  |  |  |
|  | The following   | g fees have been submitted                       |  | <del>-</del>           | CALCULATIONS | PTO USE ONLY             |  |  |  |
|  | 21. Sasic nat   | tional fee                                       | <sup>\$</sup> 300                                |                        |              |                          |  |  |  |
|  | 22.  Examinati  | ion fee  |  |                        |              |                          |  |  |  |
|  | If International prelim   | inary examination report prep                    | ared by USPTO and all claims                     |                        | \$ 000       |                          |  |  |  |
|  |   | (4)  | ໍ 200  |                        |              |                          |  |  |  |
|  | 23. Search fe   |  |  |                        |              |                          |  |  |  |
|  | ▼ 1   | .445(a)(2)) has been paid on                     |  |                        |              |                          |  |  |  |
|  | International S   | Searching Authority Report prepared and provided |  |                        |              |                          |  |  |  |
|  |   |  | \$ 400   |                        |              |                          |  |  |  |
|  | TOTAL OF 21, 22 and 23 =  |  |  |                        | \$ 900       |                          |  |  |  |
|  | Additional fee for  | specification and drawings file                  | -  |                        |              |                          |  |  |  |
| sequence listing or computer program listing filed in an electronic medium).  The fee is \$250 for each additional 50 sheets of paper or fraction thereof.   |   |  |  |                        |              |                          |  |  |  |
|  |   |  |  | RATE                   |              |                          |  |  |  |
|  | Total Sheets L  |  | up to a whole number)                            | 10112                  |              |                          |  |  |  |
|  | - 100 =   | /50 =  |  | x \$250                | \$           |                          |  |  |  |
|  |   | for furnishing the oath or dec                   | \$   |                        |              |                          |  |  |  |
|  | claimed priority date (   |  |  | <u> </u>               |              |                          |  |  |  |
|  | CLAIMS  | NUMBER FILED                                     | NUMBER EXTRA                                     | RATE                   | \$           |                          |  |  |  |
|  | Total claims  | 54 - 20 =  | 34   | x \$ 50                | \$ 1700      |                          |  |  |  |
|  | Independent claims  | 8 -3=  | 5  | x \$200                | \$ 1000      |                          |  |  |  |
|  | MULTIPLE DEPENDE  | ENT CLAIM(S) (if applicable)                     |  | + \$360                | \$           |                          |  |  |  |
| TOTAL OF ABOVE CALCULATIONS = \$3,600  |   |  |  |                        |              |                          |  |  |  |
|  | ✓ Applicant claims:   | small entity status. See 37 CF                   | -\$1,800   |                        |              |                          |  |  |  |
|  |   |  | \$ 1,800   |                        |              |                          |  |  |  |
|  | Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest  |  |  |                        |              |                          |  |  |  |
|  | claimed priority date (37 CFR 1.492(i)).  |  |  |                        |              |                          |  |  |  |
|  | TOTAL NATIONAL FEE = \$ 1,800   |  |  |                        |              |                          |  |  |  |
|  | Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property                    |  |  |                        |              |                          |  |  |  |
|  | by an appropriate cov   | er sheet (37 GFR 3.20, 3.31).                    |  |                        |              |                          |  |  |  |
|  |   |  | \$ 1,800   |                        |              |                          |  |  |  |
|  |   |  |  | Amount to be refunded: | \$           |                          |  |  |  |
|  |   |  |  |                        | Amount to be | s                        |  |  |  |
|  |   |  |  |                        | charged:     | <u></u>                  |  |  |  |
|  | a. A check in the amount of \$ to cover the above fees is enclosed.   |  |  |                        |              |                          |  |  |  |
|  | b. Please charge my Deposit Account No in the amount of \$ to cover the above fees.   |  |  |                        |              |                          |  |  |  |
|  | A duplicate copy of this sheet is enclosed.   |  |  |                        |              |                          |  |  |  |
|  | c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No A duplicate copy of this sheet is enclosed. |  |  |                        |              |                          |  |  |  |
| d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. |   |  |  |                        |              |                          |  |  |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed   |   |  |  |                        |              |                          |  |  |  |
|  | and granted to restore the International Application to pending status.  SEND ALL CORRESPONDENCE TO:  |  |  |                        |              |                          |  |  |  |
|  | 5/30/06 SICNATION   |  |  |                        |              |                          |  |  |  |
| Cheryl H. Agris, Ph.D  |   |  |  |                        | H Aarie      |                          |  |  |  |
| P.O. Box 806 Pelham, NY 10803 NAME   |   |  |  |                        |              |                          |  |  |  |
|  | •   |  | 6  |                        |              |                          |  |  |  |
|  | Custome   | r No. 25538                                      | ON NUMBER  |                        |              |                          |  |  |  |
| 1  |   |  |  |                        |              |                          |  |  |  |

Attorney Docket No.: LP-31010-US

**PATENT** 

## IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

INTERNATIONAL APPLICATION NO. PCT/DK2004/000844

INTERNATIONAL FILING DATE: 3 December 2004

PRIORITY DATE: 3 December 2003

TITLE: PHARMACEUTICAL COMPOSITIONS COMPRISING DANAZOL

APPLICANT(S) FOR RO/US: HOLM, Per and NORLING, Tomas

## **EXPRESS MAIL CERTIFICATE**

Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Express Mail Label No. EV746361574US

Date of Deposit: May 30, 2006

I hereby certify that the following attached paper(s) or fee

- 1. Transmittal Letter to the DO/EO/US
- 2. Preliminary Amendment
- 3. PTO 2038 (Fee of \$1,800.00)
- 4. Declaration and Power of Attorney (unexecuted)
- 5. Copy of International Search Report and Written Opinion of the Searching

Authority

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Cheryl H. Agris
(Name of person mailing paper(s) or fee)

(Signature of person mailing paper(s) or fee)

Mailing address: P.O. Box 806, Pelham, N.Y. 10803; telephone: (914) 712-0093